IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC. and ALLERGAN INDUSTRIE SAS, Plaintiffs, v. PROLLENIUM US INC. and PROLLENIUM MEDICAL TECHNOLOGIES INC., Defendants.	)	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Allergan USA, Inc. and Allergan Industrie SAS (collectively, "Allergan" or "Plaintiffs"), for their complaint against Defendants Prollenium US Inc. ("PUS") and Prollenium Medical Technologies, Inc. ("PMT") (PUS and PMT collectively "Prollenium"), hereby allege as follows and demand a jury trial on all issues so triable.

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 10,391,202 ("the '202 Patent") and 10,485,896 ("the '896 Patent"), which arises under the Patent Laws of the United States, Title 35, United States Code, §§ 100 *et seq.*, including 35 U.S.C. §§ 271 and 281.

PARTIES

2. Allergan USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

3. Allergan Industrie SAS is a company incorporated in France, with a principal place of business at Route de Promery, 254 ZA Pre Mairy, 74370 Pringy, France.

4. On information and belief, Prollenium US Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 9121 Anson Way, Suite 200, Raleigh, North Carolina 27615.

5. On information and belief, Prollenium Medical Technologies Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 138 Industrial Parkway N, Aurora, Ontario Canada.

6. On information and belief, Prollenium US Inc. is a subsidiary of Prollenium Medical Technologies Inc.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under patent laws of the United States including 35 U.S.C. §§ 271 and 281.

8. On information and belief, this Court has jurisdiction over Prollenium. On information and belief, PUS is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Raleigh, North Carolina. On information and belief, PMT is a foreign corporation organized and existing under the laws of Canada.

9. On information and belief, Prollenium has placed infringing products into the stream of commerce by manufacturing, shipping, importing, offering for sale and/or selling those products in this judicial district and/or knowing that such products would be manufactured, imported and/or shipped into this judicial district to be offered for sale and/or sold in this judicial district.

10. On information and belief, Prollenium has made, used, sold, offered to sell, and/or imported into this judicial district products that infringe the ’202 and ’896 Patents in this district.

11. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

The Patents-In-Suit

12. The ’202 Patent, titled “Hyaluronic Acid-Based Gels Including Lidocaine,” was duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on August 27, 2019. A true and correct copy of the ’202 Patent is attached to this complaint as Exhibit A.

13. The ’202 Patent is assigned to Allergan Industrie SAS.

14. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the ’202 Patent.

15. Allergan USA, Inc. is the exclusive licensee of the ’202 Patent.

16. The ’896 Patent, titled “Hyaluronic Acid-Based Gels Including Lidocaine,” was duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on November 26, 2019. A true and correct copy of the ’896 Patent is attached to this complaint as Exhibit B.

17. The ’896 Patent is assigned to Allergan Industrie SAS.

18. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the ’896 Patent.

19. Allergan USA, Inc. is the exclusive licensee of the ’896 Patent.

20. The ’202 and ’896 Patents are directed to dermal and subdermal fillers based on hyaluronic acid and pharmaceutically acceptable salts thereof. Dermal fillers are compositions that are injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth.

21. Hyaluronic acid-based compositions are injected into patients. These injections can cause discomfort. The use of therapeutic agents, such as anesthetic agents like lidocaine, to mitigate the pain experience upon injection was desirable. However, prior hyaluronic acid-based compositions that attempted to include lidocaine during the manufacturing process were unsuccessful because they were prone to partial or almost complete degradation prior to injection. The ’202 and ’896 Patents represent, among other things, inventions of formulations for and methods of manufacturing hyaluronic acid-based compositions that include lidocaine.

Allergan’s Hyaluronic Acid + Lidocaine Products

22. Allergan is a leading developer, manufacturer, and distributor of dermal filler products in the United States. Among those products are JUVEDÉRM® Ultra XC, JUVEDÉRM® Ultra Plus XC, and JUVEDÉRM® VOLUMA® XC (together, “Allergan’s JUVEDÉRM® Products”).

23. Allergan’s JUVEDÉRM® Products are injectable hyaluronic acid gels that contain a small quantity of local anesthetic, lidocaine. Allergan’s JUVEDÉRM® Products temporarily add volume to facial tissue and restore a smoother appearance to the face. The lidocaine included in the gel improves the comfort of the injection. The effects of Allergan’s JUVEDÉRM® Products last about 9 months to 1 year. Allergan’s JUVEDÉRM® Products were approved by the U.S. Food and Drug Administration to last up to one year from initial treatment. Allergan’s JUVEDÉRM® Products account for more than $500 million of sales per year in the United States.

24. Allergan has published a webpage located at https://www.allergan.com/about/patent-notices on which it gives notice to the public that its JUVEDÉRM® Products are patented, and more particularly by patents that include the ’202 Patent and the ’896 Patent.

PROLLENIUM'S ACCUSED PRODUCTS

25. On information and belief, Prollenium makes, uses, sells, offers to sell, and/or imports into the United States Revanesse® Versa+TM, a dermal filler. (*See* Exhibit C, Prollenium Press Release, dated Dec. 17, 2018, available at https://www.prnewswire.com/news-releases/prollenium-us-announces-the-release-of-revanesse-versa--with-lidocaine-300767213.html). On information and belief, Revanesse® Versa+TM is an injectable hyaluronic acid gel that includes lidocaine, and is indicated for the correction of moderate to severe facial wrinkles and folds. (*See id*.)

26. As used hereinafter, the phrase "Accused Products" shall mean Revanesse® Versa+TM dermal filler products.

27. The Accused Products, and the method of making the Accused Products, satisfy all of the elements of one or more of the claims of each of the '202 and '896 Patents. For example, the Accused Products infringe at least claim 9 of the '202 Patent and claims 1, 16, 24, and 25 of the '896 Patent.

28. The Accused Products infringe claim 9 of the '202 Patent because, literally or under the doctrine of equivalents, they include a stable, sterile soft tissue filler comprising: a hyaluronic acid (HA) component comprising HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and uncrosslinked HA; and lidocaine at a concentration of about 0.3% by weight of the soft tissue filler combined with said crosslinked HA component; wherein the soft tissue filler is stable after heat sterilization at between about 120 degrees C. and about 130 degrees C.; and wherein the soft tissue filler has a pH of about 7; and wherein the stable, sterile soft tissue filler is made by a process comprising: providing the HA component crosslinked with BDDE, adding a solution containing lidocaine to the HA component crosslinked with BDDE to obtain a soft tissue filler, and heat sterilizing the soft tissue filler to obtain a stable, sterile soft tissue filler.

29. The Accused Products infringe claim 1 of the ’896 Patent because, literally or under the doctrine of equivalents, they include a dermal filler composition comprising hyaluronic acid (HA) crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and lidocaine is freely released in vivo, wherein the dermal filler is sterile, and wherein the dermal filler is made by a process comprising: crosslinking HA with BDDE to obtain a crosslinked HA composition, adding lidocaine to the crosslinked HA composition, and heat sterilizing the crosslinked HA composition with the added lidocaine to obtain a sterile dermal filler.

30. The Accused Products infringe claim 16 of the ’896 Patent because, literally or under the doctrine of equivalents, they include a dermal filler composition comprising a composition comprising hyaluronic acid (HA) crosslinked with 1,4 butanediol diglycidyl ether (BDDE), wherein the HA is not crosslinked to a non-HA biopolymer, and lidocaine; wherein the dermal filler is made by a process comprising: crosslinking HA with BDDE to obtain a crosslinked HA; adding lidocaine to the crosslinked HA; and heat sterilizing the crosslinked HA with added lidocaine to obtain a sterile dermal filler.

31. The Accused Products infringe claim 24 of the ’896 Patent because, literally or under the doctrine of equivalents, they include a dermal filler composition comprising: a hyaluronic acid (HA) crosslinked with 1,4 butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine by weight, wherein the lidocaine is freely released in vivo and wherein the composition is sterile; wherein the composition is made by a process comprising: crosslinking HA with BDDE to obtain a crosslinked HA; adding a free HA gel to the crosslinked HA; adding a solution of lidocaine HC1 to the crosslinked HA; and autoclaving the crosslinked HA having free HA gel and lidocaine HC1 added thereto, to obtain a sterile dermal filler composition.

32. The Accused Products infringe claim 25 of the ’896 Patent because, literally or under the doctrine of equivalents, they include a dermal filler product comprising: a dermal filler composition comprising a hyaluronic acid (HA) crosslinked with 1,4 butanediol diglycidyl ether (BDDE), and between about 0.1% to about 5.0% lidocaine by weight, wherein the HA is not crosslinked to a non-HA biopolymer, and wherein the composition is sterile; a syringe containing the sterile composition; wherein the product is made by a process comprising: crosslinking HA with BDDE to obtain a crosslinked HA; adding lidocaine to the crosslinked HA to obtain a crosslinked HA containing lidocaine; and packaging the crosslinked HA containing lidocaine in a syringe; and autoclaving the syringe containing the crosslinked HA containing lidocaine to obtain a dermal filler product.

33. In addition to the foregoing examples, the Accused Products infringe other claims of each of the ’202 and ’896 Patents.

34. On information and belief, PUS makes, uses, offers for sale, sells, and/or imports the Accused Products in the United States, including within this district, and/or imports the Accused Products into the United States.

35. On information and belief, PMT manufactures the Accused Products in Canada and acts in concert with and/or directs PUS regarding the manufacture, use, offer for sale, sale, and/or import of the Accused Products into the United States.

36. On information and belief, Prollenium was aware of Allergan’s JUVEDÉRM® Products that practice the ’202 and ’896 Patents at least as early as August 2016. Additionally, Prollenium was aware of Allergan’s JUVEDÉRM® Products that practice the ’202 and ’896 Patents at least as early as January 22, 2019, when Allergan filed suit against Prollenium

asserting infringement of patents related to the ’202 and ’896 Patents in the case captioned *Allergan USA, Inc. et al. v. Prollenium US Inc. et al.*, No. 19-126-CFC (D. Del.).

37. On information and belief, because Prollenium was aware of Allergan’s JUVEDÉRM® Products at least as early as August 2016, Prollenium was also aware of the ’202 and ’896 Patents when they issued as a result of, at least, patent marking, including marking on the webpage located at https://www.allergan.com/about/patent-notices.

COUNT I
(Infringement of the ’202 Patent Under 35 U.S.C. §271)

38. Allergan incorporates fully herein paragraphs 1 to 37 as set forth above.

39. Prollenium has been and is directly infringing the claims of the ’202 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

40. On information and belief, Prollenium has induced, and continues to induce, infringement of the ’202 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the ’202 Patent. On information and belief, those customers or healthcare providers in fact infringe the ’202 Patent by using the Accused Products in the United States. Prollenium has engaged in those activities with knowledge of the ’202 Patent and specific intent to infringe that patent.

41. Prollenium does not have a license to practice the subject matter claimed by the ’202 Patent. Prollenium does not have any other authority to practice the subject matter claimed by the ’202 Patent.

42. Upon information and belief, Prollenium has been aware of the ’202 Patent since August 27, 2019 and has continued its infringement thereafter.

43. Upon information and belief, Prollenium has willfully infringed the ’202 Patent. Prollenium’s willful infringement of the ’202 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

44. As a result of Prollenium’s infringement of the ’202 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prollenium the damages adequate to compensate for such infringement, which have yet to be determined.

45. Prollenium’s acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prollenium’s infringement of the ’202 Patent. Considering the balance of hardships between Allergan and Prollenium, an injunction is warranted because the hardships that would be imposed upon Prollenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served by issuance of an injunction. Prollenium’s infringement of the ’202 Patent has also caused damages in an amount to be determined at trial.

COUNT II
(Infringement of the ’896 Patent Under 35 U.S.C. §271)

46. Allergan incorporates fully herein paragraphs 1 to 45 as set forth above.

47. Prollenium has been and is directly infringing the claims of the ’896 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

48. On information and belief, Prollenium has induced, and continues to induce, infringement of the ’896 Patent by actively encouraging customers or healthcare providers to use

the Accused Products in the United States with knowledge that such use would infringe the ’896 Patent. On information and belief, those customers or healthcare providers in fact infringe the ’896 Patent by using the Accused Products in the United States. Prollenium has engaged in those activities with knowledge of the ’896 Patent and specific intent to infringe that patent.

49. Prollenium does not have a license to practice the subject matter claimed by the ’896 Patent. Prollenium does not have any other authority to practice the subject matter claimed by the ’896 Patent.

50. Upon information and belief, Prollenium has been aware of the ’896 Patent since November 26, 2019 and has continued its infringement thereafter.

51. Upon information and belief, Prollenium has willfully infringed the ’896 Patent. Prollenium’s willful infringement of the ’896 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

52. As a result of Prollenium’s infringement of the ’896 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prollenium the damages adequate to compensate for such infringement, which have yet to be determined.

53. Prollenium’s acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prollenium’s infringement of the ’896 Patent. Considering the balance of hardships between Allergan and Prollenium, an injunction is warranted because the hardships that would be imposed upon Prollenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served

by issuance of an injunction. Prollenium's infringement of the '896 Patent has also caused damages in an amount to be determined at trial.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

Allergan respectfully requests that this Court enter judgment and provide relief as follows:

a. Adjudging that Prollenium has directly infringed the '202 and '896 Patents;

b. Adjudging that Prollenium has induced infringement of the '202 and '896 Patents;

c. Permanently enjoining Prollenium, and its respective officers, agents, servants, employees, attorneys, and all persons in active concert or participation with any of them directly or indirectly, from making, using, offering for sale and/or selling within the United States, and/or importing into the United States, the Accused Products and any products that infringe or induce the infringement of the '202 and '896 Patents prior to the expiration of those patents, including any extensions;

d. Awarding Allergan damages from Prollenium in amounts sufficient to compensate it for Prollenium's infringement of the '202 and '896 Patents, together with prejudgment and post judgment interest and costs, pursuant to 35 U.S.C. § 284;

e. Ordering that Prollenium to account for additional damages for any and all periods of infringement not included in the damages awarded by the Court or jury, including specifically any time periods between any order or verdict awarding damages and entry of final judgment;

f. Adjudging that Prollenium has willfully infringed the ’202 and ’896 Patents and trebling the damages awarded for Prollenium’s infringement pursuant to 35 U.S.C. § 284;

g. Declaring that this is an exceptional case under 35 U.S.C. § 285, and Allergan be awarded reasonable attorneys’ fees and costs incurred in this action; and

h. Awarding Allergan such other equitable or legal relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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